



Proposed Regulation Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-130-10 et seq.
Regulation title	Regulations Governing the Practice of Licensed Midwives
Action title	Disclosures of risks to certain clients
Date this document prepared	6/23/10

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The Board of Medicine, with unanimous approval from the Advisory Board on Midwifery, approved proposed regulations to require midwives to disclose to their clients, when certain antepartum or intrapartum conditions exist, options for consultation and referral to a physician and evidence-based information on health risks associated with a home birth.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

- 1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
- 2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
- 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
- ...*
- 6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...*

A specific regulatory mandate for the Board of Medicine is found in § 54.1.2957.9:

§ [54.1-2957.9](#). Regulation of the practice of midwifery.

*The Board shall adopt regulations governing the practice of midwifery, upon consultation with the Advisory Board on Midwifery. The regulations shall (i) address the requirements for licensure to practice midwifery, including the establishment of standards of care, (ii) be consistent with the North American Registry of Midwives' current job description for the profession and the National Association of Certified Professional Midwives' standards of practice, except that prescriptive authority and the possession and administration of controlled substances shall be prohibited, (iii) ensure independent practice, (iv) **require midwives to disclose to their patients, when appropriate, options for consultation and referral to a physician and evidence-based information on health risks associated with birth of a child outside of a hospital or birthing center, as defined in subsection E of § [32.1-11.5](#), including but not limited to risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple gestation,** (v) provide for an appropriate license fee, and ~~(v)~~ (vi) include requirements for licensure renewal and continuing education. Such regulations shall not (a) require any agreement, written or otherwise, with another health care professional or (b) require the assessment of a woman who is seeking midwifery services by another health care professional.*

License renewal shall be contingent upon maintaining a Certified Professional Midwife certification.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The purpose of the planned regulatory action is compliance with a legislative mandate for the adoption of regulations relating to disclosures of risk to certain patients. The law was amended by HB2163 (Chapter 646 of the 2009 Acts of the Assembly) to require the Board to adopt regulations governing the practice of midwifery, upon consultation with the Advisory Board on Midwifery. The regulations shall require midwives to “*disclose to their patients, when appropriate, options for consultation and referral to a physician and evidence-based information on health risks associated with birth of a child outside of a hospital or birthing center, as defined in subsection E of § 32.1-11.5, including but not limited to risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple gestation.*”

The amendments set out the conditions or risks factors for which it is “appropriate” to disclose the options available for referral and consultation and to provide the evidence-based information to a client about risks associated with birth outside of a hospital or birthing center for women with certain conditions or clinical situations.

In Virginia, the Code requires that regulations to be consistent with the North American Registry of Midwives' (NARM) current job description for the profession. The NARM Position Paper on the Practice of Midwifery states that: “Certified Professional Midwives (CPMs) ...have demonstrated the knowledge and skills to provide full prenatal, birth, and postpartum care to low-risk women, to recognize deviations from normal, and to refer, consult, or transfer care if appropriate.” The proposed regulation is consistent with the NARM model in which midwives are expected to appropriately assess deviations from the normal and to disclose to clients those conditions or situations in which an out-of-hospital birth is not appropriate or those that may present certain risks to a woman or her baby.

The goal for the amended regulation is to ensure that women are adequately informed of any risk for home birth associated with certain health conditions or prior birth history. Regulation of risk disclosure requires that women are adequately assessed and informed of the condition which presents increased risk for home birth and ensure that the choice of provider and birth setting are made with full disclosure of risk.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the “Detail of changes” section.)

The proposed regulations include the following:

- 1) A requirement that, upon initiation of care, the midwife review the woman's medical history, including records from prior pregnancies in order to identify pre-existing conditions that require disclosure of risk for home birth. The midwife will also

be required to continually assess the pregnant woman in order to recognize conditions that may arise during the course of care that require disclosure of risk for home birth.

- 2) A listing of those factors or criteria that require disclosure that the client is not an appropriate candidate for an out-of-hospital birth, and a listing of those factors or criteria that require disclosure relating options for consultation and referral.
- 3) If the factors or criteria have been identified that may indicate health risks associated with birth of a child outside a hospital, a requirement for the midwife to provide evidence-based information on such risks. Such information would be specified by the Board for certain conditions and would include statements and evidence from both the medical and midwifery models of care.
- 4) A requirement for documentation in the client record of the assessment, the presence or absence of high risks, and, if appropriate the provision of disclosures and evidence-based information.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

- 1) The primary advantage to the public (clients of midwifery) is the assurance that an appropriate assessment of health risks has been made and documented, that disclosure of such risks has been given to the client, and that evidence-based information on risks has been made available. The advantage to licensed midwives is the existence of a clear regulatory standard by which to practice. There are no disadvantages, because consumer choice will not be abridged.
- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) There are no other pertinent matters of interest.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities affected.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, or Elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. Comments may also be submitted on the Regulatory Townhall at: www.townhall.virginia.gov In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</p>	<p>a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur some one-time costs (less than \$1,000) for</p>
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	<p>mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little costs involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. The on-going expenditures related to licensure and discipline are incorporated into the budget of the Board of Medicine. Fees for midwives are intended to be sufficient to cover expenditures.</p>
<p>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</p>	<p>There are no costs to localities.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.</p>	<p>Midwives licensed by the Board of Medicine</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are 49 midwives licensed in Virginia; all will be affected by the requirements for disclosure and provision of evidence-based information. All practice independently and would be considered a small business.</p>
<p>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>The statute requires the midwife to provide “evidence-based information on health risks associated with birth of a child outside of a hospital or birthing center.” Regulations specify that the information will be determined in the form of guidance documents that may be adopted by the Board of Medicine and may be revised as new evidence and research becomes available. The regulations specify that the evidence-based information must represent both the medical and midwifery models of care. Guidance documents will be made available electronically on the Board website and notice sent to midwives of their availability. As needed, midwives can download the guidance (evidence-based information) and provide to clients. There should be no costs involved for the midwives or clients.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>The beneficial impact is a clearer standard for midwives to follow and appropriate disclosures and evidence-based information about risks for clients.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no viable alternatives to the proposed regulatory action as it is mandated by the Code of Virginia.

In the development of regulations, the Advisory Board considered standards adopted in other states. Many states require practice with a collaborating physician, referral to a physician at certain points in the pregnancy or whenever the woman presents with certain conditions, or prohibit a licensed midwife from providing care to women with specified high risk conditions. The proposed regulations implementing HB2163 do not contain such prohibitions or requirements, but are focused on assessment and recognition of risks, provision of evidence-based information and disclosure to clients the options appropriate to those risks.

The proposed regulations were developed by an ad hoc committee, comprised of two licensed midwives and an obstetrician, who was President of the Board of Medicine. The model used for a listing of risk factors or conditions requiring disclosure was regulation in Oregon, in which midwifery has been widely-recognized and long-regulated. Oregon requires every licensed midwife to assess the appropriateness of an out-of-hospital birth for each client, taking into account the health and condition of the mother and fetus or baby.

During development of proposed regulations, a draft was shared with the CMA-CPM Guild, a newly formed group comprised solely of licensed Virginia midwives (CPM's) within the Commonwealth Midwives Alliance (which includes consumers and midwives). That group suggested edits, which were incorporated into the draft. After numerous drafts and redrafts, the ad hoc committee unanimously recommended the amendments to the Advisory Board on Midwifery, which unanimously recommended adoption to the full Board of Medicine. The Board then approved the proposal without dissent.

Interested parties, from both medicine and midwifery, had the opportunity to comment on the Notice of Intended Regulatory Action and were involved in the development of language to implement the legislative mandate.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

Mandated by the statute, the Board has no alternative regulatory methods. ***"The Board shall adopt regulations governing the practice of midwifery, upon consultation with the Advisory Board on Midwifery. The regulations shall... (iv) require midwives to disclose to their patients, when appropriate, options for consultation and referral to a physician and evidence-based information on health risks associated with birth of a child outside of a hospital or birthing***

center, as defined in subsection E of § 32.1-11.5, including but not limited to risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple gestation.”

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Brynne Potter	Commends the Board’s efforts to bring medical and midwifery communities together in development of regulations. Encourages the use of objective, quality research in information to be provided and suggests that there should be ways to provide updates as new research and understanding develops.	The Board agrees with the comment and has incorporated the need for updates of evidence-based information through the adoption of guidance documents.
Maddy Oden	Supports choice of home births; informed choice should include risks and benefits of birth in a home and hospital	The Board acknowledges the comment; the statutory mandate is for regulations that provide information about the risks of home births for certain conditions
Maryann Combs	Commends the Board for ensuring that women have access to evidence-based informed consent.	The Board acknowledges the comment.
Dr. Lori Flanagan	Should expand the requirement for factual information to all members of maternity system – including doctors and hospitals	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Jennifer Cassell	Supports involving regulations for evidence-based informed consent; should include regulation for all women to received risks of hospital births.	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Maddy Cassell	Supports inclusion of regulations for all women to received risks of hospital births.	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Jenne Alderks	Commends ensuring that women are supplied with unbiased information on which to base their choice of birth setting. Should have same requirements for informed consent for those attending births in hospitals	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Grainne Ostrowski	There should be scientific research provided on the risks and benefits, including risks in the hospital. Pregnant women should make a well-informed choice.	The Board acknowledges the comment.
Tami Conklin	Supports the idea that ALL birth care providers should present their clients or patients with research-based facts concerning the possible outcomes and effects of every procedure and health condition they encounter during pregnancy	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Virginia Ferguson	The midwife should be required to inform me of all the options I have, the	The Board acknowledges the comment.

	rights I have, and let me know if there could be side effects from any treatment she suggested	
Tammi McKinley	The Board of Medicine should use data from well-designed, well-executed studies in formulating the information and disclosures that will be required of CPMs. One source is the Agency for Healthcare Research and Quality (AHRQ) which continually looks at the data available by topic and the quality of the data available in making its recommendations for evidence-based practice.	The Board acknowledges the comment and will consider the recommended source in drafting guidance documents.
Kristen Marsh	This action should be taken of ALL health care providers and not single out CPMs.	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Pamela H. Pilch	The Board of Medicine should be educated by the Certified Professional Midwives involved in the process about their practices and protocols, and the evidence that underpins it. Rely on good quality evidence, including that coming from the Cochrane database and the Agency for Healthcare Research and Quality (AHRQ).	The Board acknowledges the comment and will consider the recommended source in drafting guidance documents.
Aimee L. Crane	This proposed change is clearly redundant to the obligations to which all of Virginia's Licensed Midwives are already bound under the pre-existing Midwifery Model of Care. Should not impinge on consumer's rights or waste the taxpayer's money by adopting these unnecessary regulations.	A midwife who is currently meeting the standards set forth in Section 86 will have no further obligation. There is no impingement on consumer rights in these regulations, which are not adopted using any taxpayer money.
Denton Romans	The critical element is that the risks/benefits be evidence based - published studies in reputable journals. Any regulation should include disclosure requirements for both hospital and home births.	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Sara Fariss Krivanec	It is imperative that informed choice includes the risks and <u>benefits</u> of home birth and that any "evidence" be based on research, not the obstetrical standard of care.	Evidence-based information will include both the midwifery and the medical standard of care.
Calli Curtis	Having evidence-based information is the best possible antidote for misinformation and it protects our freedom of choice	The Board acknowledges the comment.
Rebecca Aquino	The evidence supports the safety of home-birth, even in many "high-risk" cases. I do not believe any more regulation is necessary.	The Board has a statutory mandate to adopt regulations on disclosure and options for consultation.
Dawn Kubik	Informed consent is critical for all women to be able to choose the safest place for them to birth. It is my hope that requirements/enforcement for informed consent will be made for OBs as well.	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Michele Sullivan	The consumer should see full	The Board acknowledges the comment.

	information for informed consent, including the risks <u>and benefits</u> of home birth, AND of hospital births. I want the evidence to be based on research, not opinion.	
John Smith	Parents should always be given the full facts as far as they are known and any regulation should include disclosure requirements for both hospital and home births.	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Kelly Valceanu	Doctors should be informed choice, not informed consent. Families will choose the safest choices if they are given adequate, evidence based research.	The Board acknowledges the comment.
Maria Hishikawa	The Midwifery Model of Care already incorporates full disclosure of risks and benefits of all alternative options and treatments, then allows the patient to make decisions without pressure.	Midwives who currently practice in accordance with standards set forth in Section 86 will have no further requirements.
Michelle Byrom	Fully supports true informed consent for all healthcare providers. All care providers should offer evidence-based, accurate, unbiased information for birthing families to use to make their own educated choices.	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Vickie Liguori	Regulations are redundant; our regulations already demand Informed Consent. The proposed additions do provide an opportunity for evidence-based informed consent to be required of all health care providers in the State, especially in regards to maternity care providers. It is also an opportunity to clarify, that even in unusual or difficult circumstances, clients need to be provided with the information that they need in order to make the best decision for them and their family.	Midwives who currently practice in accordance with standards set forth in Section 86 will have no further requirements. The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Sabrina McIntyre	The CPMs informed me of any and all risks, procedures and general expectations during my initial prenatal visits and any there after.	The Board acknowledges the comment.
Janelle Seymour	Please make sure this applies to obstetricians as well as midwives, because ALL women have the right to true informed consent when making choices about their own bodies and the lives of their babies	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; its mandate did not extend to other providers.
Kim Pekin	The proposed regulatory action is redundant and its implementation is costly to taxpayers. Evidence-based information should be objective come from sources such as the Cochrane Database and the Agency for Healthcare Research and Quality (AHRQ).	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives; there are no taxpayer dollars involved. The Board will consider the recommended sources for information.
Gina Bass	Disclosure is a hallmark of midwifery care.	Midwives who currently practice in accordance with standards set forth in Section 86 will have no further requirements.
Jennifer Downey	Drafters should be exceedingly careful to base the substance of the required information on objective evidence,	The Board acknowledges the comment and will consider it as guidance documents are drafted.

	rather than subjective opinion	
Peggy Franklin	The amendments should preserve the midwifery model of care and client's freedom of choice	The Board acknowledges the comment.
Jill Carrillo	Supports true informed consent for all healthcare providers. Redundant for midwives	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives. Midwives who currently practice in accordance with standards set forth in Section 86 will have no further requirements.
Melissa Fawley	Informed consent should be available to all women.	The Board acknowledges the comment.
Amy Ferguson	Supports true informed consent for all healthcare providers.	The Board acknowledges the comment.
Freeda Cathcart	In order to have true informed consent, the evidence based research must be compiled from quality studies.	The Board acknowledges the comment.
Beth Ashton	Informed consent requirements redundant for midwives; an improper government intrusion into the practice of midwifery	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives. Midwives who currently practice in accordance with standards set forth in Section 86 will have no further requirements.
Kelly Elder	Women must be given research-based information to make an informed choice	The Board acknowledges the comment.
Becky Banks	Favors evidence-based guidelines for risk for birth, but more regulation will put more limitation and less choice for women.	The Board has a statutory mandate to adopt regulations on disclosure on home births for licensed midwives. Midwives who currently practice in accordance with standards set forth in Section 86 will have no further requirements.
Trinlie Wood	Responsibility for implementation of legislative mandate should be with CPM's	CPM's have developed regulations in collaboration with board members.
Carol Sakala	Suggests use of a report by her group (Childbirth Connection) on maternity care in U.S.	The report will be considered in the development of guidance documents.
Aimee Fairman	Informed consent is a cornerstone of midwifery model of care	The Board acknowledges the comment.
Lisa Pratt	Reconsider passing this regulation that is harmful to women	The Board has a statutory mandate for regulation on disclosure.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed regulatory action has no impact on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if

implemented in each section. Please detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
85	n/a	Section sets out disclosure requirements	Changes the name of the section so it references the <u>general</u> disclosure requirements and new section 86 sets out the disclosure requirements for certain high risk conditions.
n/a	86	Sections sets out disclosure requirements for certain health conditions	<p>Subsection A:</p> <ul style="list-style-type: none"> • Requires the midwife, upon initiation of care, to review the client's medical history in order to identify pre-existing conditions or indicators that require disclosure of risk for home birth. • Requires the midwife to offer standard tests and screenings for evaluating risks and to document client response to such recommendations. • Requires the midwife to continually assess the pregnant woman and baby in order to recognize conditions that may arise during the course of care that require disclosure of risk for birth outside of a hospital or birthing center. <p><i>Subsection A is intended to establish the framework for care that is reasonable and necessary in order to identify whether conditions or health risks are present that would trigger disclosures as required by law. There is not requirement that the midwife refer a client to another health care professional but there is a requirement for recommendation of tests and screenings necessary to evaluate risks.</i></p> <p>Subsection B:</p> <ul style="list-style-type: none"> • Requires the midwife to request and review the client’s medical history, including records of the current or previous pregnancies, disclose to the client the risks associated with a birth outside of a hospital or birthing center and provide options for consultation and referral – if the evaluation and review of medical history indicates that any of the conditions listed are present. • Requires the midwife to consult with or request documentation from the physician as part of the risk assessment for birth outside of a hospital or birthing center if the client is under the care of a physician for any of the listed medical conditions or risk factors.

			<p>Subdivision 1 lists the antepartum risks that would trigger the need for disclosure about possible risk of a home birth and the options for referral and consultation:</p> <ul style="list-style-type: none"> · Conditions requiring on-going medical supervision or on-going use of medications; · Active cancer; · Cardiac disease; · Severe renal disease -- active or chronic; · Severe liver disease -- active or chronic; · HIV positive status with AIDS; · Uncontrolled hyperthyroidism; · Chronic obstructive pulmonary disease; · Seizure disorder requiring prescriptive medication; · Psychiatric disorders; · Current substance abuse known to cause adverse effects; · Essential chronic hypertension over 140/90; · Significant glucose intolerance; · Genital herpes; · Inappropriate fetal size for gestation; · Significant 2nd or 3rd trimester bleeding; · Incomplete spontaneous abortion; · Abnormal fetal cardiac rate or rhythm; · Uterine anomaly; · Platelet count less than 120,000; · Previous uterine incision and/or myomectomy with review of surgical records and/or subsequent birth history; · Isoimmunization to blood factors; · Body Mass Index (BMI) equal to or greater than 30; · History of hemoglobinopathies; · Acute or chronic thrombophlebitis; · Anemia (hematocrit less than 30 or hemoglobin less than 10 at term; · Blood coagulation defect; · Pre-eclampsia/eclampsia; · Uterine ablation; · Placental abruption; · Placenta previa at onset of labor; · Persistent severe abnormal quantity of amniotic fluid; · Suspected chorioamnionitis; · Ectopic pregnancy; · Pregnancy lasting longer than 42 completed weeks with an abnormal non-stress test; · Any pregnancy with abnormal fetal surveillance tests; · Rupture of membranes 24 hours before the onset of labor; · Position presentation other than vertex at term or while in labor; · Multiple gestation. <p>Subdivision 2 lists the intrapartum risks that would trigger the need for disclosure about possible risk of a home birth and the options for referral and consultation:</p> <ul style="list-style-type: none"> · Current substance abuse; · Documented Intrauterine growth retardation (IUGR)/small for gestational age (SGA) at term; · Suspected uterine rupture;
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		<ul style="list-style-type: none"> · Active herpes lesion in an unprotectable area; · Prolapsed cord or cord presentation; · Suspected complete or partial placental abruption; · Suspected placental previa; · Suspected chorioamnionitis; · Pre-eclampsia/eclampsia; · Thick meconium stained amniotic fluid without reassuring fetal heart tones and birth is not imminent; · Position presentation other than vertex at term or while in labor; · Abnormal auscultated fetal heart rate pattern unresponsive to treatment or inability to auscultate fetal heart tones; · Excessive vomiting, dehydration, or exhaustion unresponsive to treatment; · Blood pressure greater than 140/90 which persists or rises and birth is not imminent; · Maternal fever equal to or greater than 100.4°; · Labor or premature rupture of membrane (PROM) less than 37 weeks according to due date. <p>Subdivision 3 specifies that if a risk factor first develops when birth is imminent, the individual midwife must use judgment taking into account the health and condition of the mother and baby in determining whether to proceed with a home birth or arrange transportation to a hospital.</p> <p><i>The listing of antepartum and intrapartum conditions or events that would necessitate a disclosure about risks of home births and the options for referral and consultation was originally taken from the midwifery rules in Oregon, but was revised and adapted for Virginia in the rulemaking process that included midwifery and obstetrics. It was agreed that the specific conditions should be listed so there was no ambiguity for midwives about their obligation to recognize and understand risk factors and to present options to their clients.</i></p> <p><i>If a client is under a physician’s care for a risk factor such as hypertension or other medical conditions, the reasonable obligation of the midwife is to consult with or request documentation from the physician as part of the risk assessment for birth outside of a hospital.</i></p> <p><i>While the presence of any of the listed conditions should indicate disclosure about risks and options for referral, the midwife is required to use her professional judgment about the risk of a home birth and the need for a transport to a hospital if the birth is imminent.</i></p> <p>Subsection C requires that if the risks factors or criteria have been identified that may indicate health risks associated with birth of a child outside a hospital or birthing center, the midwife shall provide evidence-based information on such risks. Such information shall be specified by the board in</p>
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